OPIOID CRISIS UPDATE, FENTANYL ANALOGUES AND *Burrage* Decision

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Department of Justice

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▶ To provide an overview of the opioid epidemic in the United States
▶ Discuss emerging psychoactive substances (fentanyl analogues)
▶ Explain guidelines for drug death prosecutions

No conflicts of interest
Opioid pain relievers

- A. Are a late factor in the evolution of the current epidemic of opioid mortality
- B. Were less frequently prescribed the 1990s than previous decades
- C. Were reformulated to reduce abuse potential
- D. Are not addictive if used in the treatment of chronic pain
- E. Cannot be overprescribed if a patient reports they are still experiencing pain
Three Phase Evolution of the Crisis

- Opioid Pain Relievers (~1990s-2000s)
- Heroin (~2010-2014)
- Fentanyl/ Fentanyl Analogues (~2014- )

OPIOID CRISIS EVOLUTION
OPIOID CRISIS EVOLUTION

- Opioid Pain Reliever Phase
  - Liberalization of prescribing
  - Diversion of drugs/“Pill mills”
  - Rising mortality
Annual Opioid Prescriptions
1992-2016

Some states have more opioid prescriptions per person than others.

Number of opioid prescriptions per 100 people

- 52-71
- 72-82.1
- 82.2-95
- 96-143

SOURCE: IMS, National Prescription Audit (NPA™), 2012.
Figure 1. Age-adjusted drug-poisoning and opioid-analgesic poisoning death rates: United States, 1999–2011

NOTES: The number of drug-poisoning deaths in 2011 was 41,340, and the number of drug-poisoning deaths in 2011 involving opioid analgesics was 16,917. Access data table for Figure 1 at: http://www.cdc.gov/nchs/data/databriefs/db166_table.pdf#1.
OPIOID CRISIS EVOLUTION

- Opioid Pain Reliever Phase
  - Regulation of prescribing
  - Drug monitoring programs
  - Abuse deterrent opioid formulations
Heroin Phase

- Restrictions on access to opioid pain relievers (OPR)
- Transition from OPR to heroin
  - Both are narcotics- similar actions
  - Increasing mortality
HEROIN

- Diacetylmorphine
- Production increases in Mexico
- Distribution rises in the United States
HEROIN-CHEMISTRY/PHARMACOLOGY

Diacetylmorphine (Heroin) → 6-monoacetylmorphine → Morphine
HEROIN

- Schedule 1 drug
  - High potential for abuse
  - No current medical use
  - Lack of accepted safety for use
HEROIN

- Typically sold as white or brown powder or as a sticky black substance known as “black tar”
- Abused by injecting, snorting or smoking
Comparing Opioid Overdose Deaths and Heroin Deaths in Cuyahoga County, 2007-2013

Source: Cuyahoga County Medical Examiner’s Office April 22, 2014
Heroin deaths spike in Ohio

A record number of Ohioans died from heroin overdoses in 2012, the latest figures available.

Number of heroin deaths per year

SOURCE: Ohio Department of Health
Fentanyl Phase

- In 2014 law enforcement agencies noted increase in fentanyl seizures
- Fentanyl began to be seen in mixtures with heroin and cocaine
- Dramatically increasing mortality
Fentanyl

- Narcotic anesthetic introduced 1960’s
- Intravenous/intramuscular/oral
- Potency
- Synthetic (non-naturally occurring product)
- 1990’s- expansion in chronic pain therapy
  - Transdermal delivery system
  - Diversion/abuse vs. illicit manufacture

**Fentanyl**
Age-adjusted drug overdose death rates, by state: United States, 2015

Opioid deaths in 2015

Age-adjusted death rates (per 100,000) for overdose deaths from all opioid drugs

Source: CDC WONDER
Synthetic opioid deaths in 2015

Age-adjusted synthetic opioid overdose death rate (per 100,000)
A 46% Increase from 2015-2016. Largely due to fentanyl, and fentanyl-laced heroin.
Along with the rise in fentanyl deaths rises were also seen in heroin mortality and cocaine mortality.

Impact of mixtures vs. individual drugs.
Cuyahoga County Overdose Deaths 2013-2017
Impact of Fentanyl

- 2013: 340 cases
- 2014: 353 cases
- 2015: 370 cases
- 2016: 666 cases
- 2017*: 727 cases

Legend:
- **Black Line**: TOTAL DRUG OD DEATHS
- **Blue Line**: Heroin
- **Cyan Line**: Non-fentanyl associated Heroin deaths
- **Green Line**: Non-fentanyl associated Cocaine deaths
- **Purple Line**: Fentanyl
- **Gold Line**: Cocaine

*Note: 2017 data is an estimate.
OPIOID CRISIS EVOLUTION

- Fentanyl/Fentanyl Analogue Phase
  - Designer drugs- rationale
  - Role of the internet and international supply
  - Continued escalating mortality
Fentanyl analogues
- Acetyl fentanyl
- Carfentanil
- Others
Fentanyl
fentanyl

carfentanil
Acetyl fentanyl

Fentanyl
### WHAT WE KNOW

**Fentanyl Substances**

<table>
<thead>
<tr>
<th>Substance</th>
<th>Date 1st Encountered</th>
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<tbody>
<tr>
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<td>U-51754</td>
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*Source: Cuyahoga County Medical Examiner's Office revised 9-15-17*
Novel Substance Identifications

CDC, Customs & Border Protection
OCDETF, and NMS Labs

<table>
<thead>
<tr>
<th>Analyte</th>
<th>Sample Type</th>
<th>Date of Report</th>
<th>Chemical Formula</th>
<th>Molecular Weight</th>
<th>Molecular Ion [M+]</th>
<th>Exact Mass [M+H]+</th>
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Acetyl Fentanyl Rhode Island 2013
Carfentanil Akron July 2016
Emergence of other Novel Psychoactive Substances (NPS)

FENTANYL/FENTANYL ANALOGUE
Mortality into 2018 has plateaued and appears to be decreasing slightly.

Impact of scheduling of analogues?

Alternate drugs (methamphetamine)

FENTANYL/FENTANYL ANALOGUE
Challenges
- Instrumentation
- Personnel
- Funding

FENTANYL/FENTANYL ANALOGUES
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Total POE Express Mail Drug Seizures:
Oct 2017- Feb 2018 (CBP)

**Opiates and Opioids**

*Total: 375.53 kg*

- **OPIUM (7100)**
- **O-DESMETHYLTRAMADOL (111.3)**
- **NOSCAPINE (3450)**
- **METHOXYACETYL FENTANYL (5459.3)**
- **FENTANYL (2864.5)**
- **HEROIN (7800.7)**
- **BUTYRYL FENTANYL (3155.3)**
- **Cyclopropyl Fentanyl (2500)**
- **Fentanyl Pill Mixture (896.7)**
- **BENZOYL FENTANYL (900.4)**
- **4-ANPP/METHOXYACETYL FENTANYL (925.3)**
- **BUPRENORPHINE (0.018)**
- **Cyclohexyl Fentanyl (1805.9)**

*Mass reported in grams of material*

*Poppy Pods not included in this chart (337kg)*
Fentanyl Analogue Scheduling

• Core Structure Scheduling
  • In December 2017, the DEA announced its intent to implement core structure scheduling.
  • Scheduling based on the key elements of fentanyl structure whether substituted to whatever extent

As set forth under 21 U.S.C. 811(h), three factors (4, 5, and 6) under the CSA (21 USC 811(c) are to be considered in the evaluation:

1. Its actual or relative potential for abuse
2. Scientific evidence of its Pharmacological effects
3. The state of the current scientific knowledge regarding the substance
4. **Its history and current pattern of abuse**
5. **The scope, duration, and significance of abuse**
6. **What, if any, risk there is to public**
7. Its psychic or physiological dependence liability
8. Whether the substance is an immediate precursor of a substance already controlled
NOTICE OF INTENT – FENTANYL RELATED SUBSTANCES
DECEMBER 29, 2017, FEDERAL REGISTER 82 FR 61700, 61700-61703,
CODIFIED INTO LAW IN FEBRUARY 2018

“The Administrator of the Drug Enforcement Administration is publishing notice of intent to issue an order temporarily scheduling fentanyl-related substances that are not currently listed in any schedule of the Controlled Substances Act. (CSA). The temporary order will pace these substances into schedule I…based on a finding…that placement of these synthetic opioids in schedule I is necessary to avoid an imminent hazard to public safety.”

Temporary scheduled is for two years, and if permanent scheduling is initiated, the period of temporary scheduling may be extended for one additional year.

“…[T]he temporary scheduling order…will include all substances that fall within the above definition—even if such substances have not yet emerged on the illicit market in the United States.”
SPECIFIC IDENTIFICATION OF ANALOGUES STILL MATTERS

“In the future, if and when the DEA identifies a specific new substance that falls under the definition, the agency will publish in the Federal Register, and on the agency website, the chemical name of the substance…it bears emphasis, however, that even in absence of future publication specifying such substance…the substance will be controlled by the temporary scheduling order if it falls with the definition of fentanyl related substance.”
Fentanyl-related substances will be defined to include any substance (not otherwise controlled in any schedule) that is structurally related to fentanyl by the following modifications:

(A) replacement of the phenyl portion of the phenethyl group by any monocycle, whether or not further substituted in or on the monocycle;

(B) substitution in or on the phenethyl group with alkyl, alkenyl, alkoxy, hydroxyl, halo, haloalkyl, amino or nitro groups;

(C) substitution in or on the piperidine ring with alkyl, alkenyl, alkoxy, ester, ether, hydroxyl, halo, haloalkyl, amino or nitro groups;

(D) replacement of the aniline ring with any aromatic monocycle whether or not further substituted in or on the aromatic monocycle; and/or

(E) replacement of the N-propionyl group by another acyl group.

The existence of any one, or any combination, of these modifications would define the substance as a fentanyl-related substance.
Fentanyl Analogs (Fentalogs)

- Acetylfentanyl
- (Fentanyl)
- F/Butyrylfentanyl
- F/Isobutyrylfentanyl
- Valerylfentanyl
- Tetrahydrofuranylhexylfentanyl
- 2/3-Furanylfentanyl
- Acrylfentanyl
- Crotonylfentanyl
- Methoxyacetylfentanyl
- Cyclopropylfentanyl
- Tetramethylcyclopropylfentanyl
- Cyclopentylfentanyl
- Cyclohexylfentanyl
- ...

Propanamide

Phenyl/aniliny

- o-Fluorofentanyl
- p-Fluorofentanyl
- ...

Carfentanil
- Alfentanil
- Sufentanil
- Remifentanil
- 3-methylfentanyl
- α-methylfentanyl
- β-hydroxyfentanyl
- β-hydroxy/Thiofentanyl
- Ethylfuranylbutylfentanyl

Phenylethyl piperidines
The *Burrage* decision;

  - Burden of “but for” causation, and what is left of “but for” causation under state law theories;
  - Mixed drug intoxications;
  - Medical expert expectations

**OPIOID CRISIS- PROSECUTIONS**
FACTS OF THE BURRAGE CASE:

- Marcus Burrage was arrested for distribution of heroin and the distribution of heroin causing the death of Joshua Banks;
- Decedent died with multiple drugs in his bloodstream, including metabolites from heroin, with that heroin being linked back to Burrage.
- Although the heroin metabolite morphine was the only drug present at levels above therapeutic range, the government could not say the decedent would have lived if he hadn’t taken the heroin. Prosecution’s expert testified that the death was caused by mixed drug intoxication.
- Burrage was found guilty of a jury and was sentenced to nearly 40 years in prison
- Conviction was appealed, and US Court of Appeals affirmed the decision of the lower court on all counts
QUESTIONS BEFORE THE COURT:

---DOES THE CRIME OF “DISTRIBUTION OF DRUGS CAUSING DEATH” REQUIRE A FORESEEABILITY OR PROXIMATE CAUSE REQUIREMENT?

-----CAN A DEFENDANT BE GUILTY OF “DISTRIBUTION OF DRUGS CAUSING DEATH” WHEN THE JURY INSTRUCTIONS FOR THAT CRIME ALLOW CONVICTION IF THE DRUG WAS A CONTRIBUTING FACTOR TO THE DEATH, BUT WAS NOT THE “BUT FOR” CAUSE OF THE DEATH?

HOLDING: 21 USC 841 requires the government to show more than that the distribution of the drug contributed to the victim’s death. The enhancement applies when “death or serious bodily injury results from the use of the distributed substance, which means the substance must be a “but for” cause of the death. Pages 887-88.
“‘BUT FOR CAUSATION’ DOES NOT REQUIRE PROOF THAT THE DISTRIBUTED DRUG WAS PRESENT IN AN AMOUNT SUFFICIENT TO KILL ON ITS OWN. DEATH CAN RESULT…FROM A PARTICULAR DRUG WHEN IT IS THE PROVERBIAL ‘STRAW THAT BROKE THE CAMEL’S BACK.’

STRICT ‘BUT FOR’ CAUSATION MIGHT NOT BE REQUIRED WHEN ‘MULTIPLE SUFFICIENT CAUSES INDEPENDENTLY, BUT CONCURRENTLY, PRODUCE A RESULT.

Since *Burrage* was decided, 1544 citing references…. 
NEW YORK TIMES, MAY 25, 2018 –HEADLINE READS:
“THEY SHARED DRUGS. SOMEONE DIED. DOES THAT MAKE THEM KILLERS?
PROSECUTORS ARE INCREASINGLY TREATING OVERDOSE DEATHS AS HOMICIDES, BUT THEY AREN’T JUST GOING AFTER DEALERS. FRIENDS, FAMILY AND FELLOW USERS ARE GOING TO PRISON.”

• In all between 2015 through 2017, NYT found that overdose prosecutions were found in 36 states, with charges ranging from involuntary manslaughter, reckless manslaughter, third, second and first-degree murder.

• In Minnesota, the number of such cases — sometimes referred to as “murder by overdose” — quadrupled over a decade.

• Pennsylvania went from 4 cases in 2011 to 171 last year after making it easier to prosecute.

• Twenty nine states allow prosecution of drug-induced homicides.
STATE LAWS IMPLICATED—DIFFERING MENTAL STATES, AND CULPABLE ACTS MAKES GENERALIZATIONS FOR BURRAGE ISSUES DIFFICULT TO IMPOSSIBLE

First Degree Murder—premeditated, after deliberation
Felony Murder—death in course of felony; proximate cause varies among states
Second Degree Murder—knowingly and intentionally caused death of victim; proximate cause required, unless accomplice or complicity theory used
Third Degree Murder—recklessly caused death of a person; proximate cause varies among state—also charged as Reckless or voluntary manslaughter in states
Involuntary Manslaughter-
Drug Induced Homicide
Drug Delivery Resulting in Death—true “Len Bias law”

New York Times Article, May 25, 2018

Then why? Paradoxically, it is about treating users, dead or alive, as important living beings, on both sides of the debate…
FEDERAL STATUTE –NO PROXIMATE CAUSE OR “REASONABLE FORESEEABILITY OF DEATH” REQUIRED FOR APPLICATION OF THE FEDERAL SENTENCING ENHANCEMENT

United States v. Harden, 893 F.3d 434 (7th Cir. (Wisconsin); June 20, 2018

--Due to the extremely hazardous nature of drug distribution, a policy of strict liability when death occurs fits the statutory language and its evident purpose.

United States v. Burkholder, 816 F.3d 607 (10th Cir. (___); ___2016

United State v. De La Cruz, 514 F.3d 121 (1st Cir. (___) ___2008

• Consistency pre- and post Burrage, and among circuits
• Important in unwitting user cases
Thomas v. State of Maryland, ___ A.3d ___, Court of Special Appeals, April 4, 2018

- Case involved Unlawful Act Manslaughter, containing an element that “the act resulting in the death of the victim occurred during the commission…of the eligible crime”.

  - Note—no hard language of “caused the death”…passive “resulting in” language, similar to Burrage language. Indeed, Thomas decision states under Maryland law, manslaughter conviction requires a causal connection with the unlawful act, and does not require that the harm / death be foreseen or intended.

  Pertinent facts: Defendant sold decedent four bags of heroin. “Later, at another time and another place, decedent injected himself with the amount of heroin he chose… in conjunction with alcohol which may have exacerbated the effect.

HOLDING: The State failed to establish a causal connection between Defendant’s sale and decedent’s death…. “Here, where the causal chain was broken, there can be no liability for the unlawful act variant of involuntary manslaughter.”
BUT, THEN AGAIN, THE EIGHTH CIRCUIT SEES IT DIFFERENTLY THAN THE MARYLAND APPELLATE COURT—

**SEE UNITED STATES V. LEWIS**, NO. 17-3046, NORTHERN DISTRICT OF IOWA, JULY 13, 2018

“Finally, Lewis argues that even if it was proven heroin caused the death to Manning, who then supplied it to Vanamburg, Stierman, and Kelly through pooled money and indirect transactions, the redistribution constitutes an intervening cause of the injuries and death for which Lewis cannot be held responsible. *Nothing in Burrage or the plain language of the statute limits the responsibility to only the last person to distribute the drug before the harm occurs.*”
Positive toxicology for benzodiazepine, cocaine metabolite, fentanyl, and opiates—no autopsy done.

Manslaughter charged based on toxicology

Forensic Pathologist One testified the toxicology results alone cannot be used to determine cause of death, and that it is possible that a person who took the amount of fentanyl taken by decedent could still be alive.

Forensic Pathologist Two testified the fentanyl level found in the decedent’s blood, per the toxicology report, was fatal and caused the death.

Jury convicted, and appellate court affirmed.
“But for causation exists where a particular substance—here, oxycodone, combines with other factors—here, diazepam and alprazolam—to result in death; without the "incremental effect of the oxycodone", the decedent wouldn’t have died.”
United States v. Roundtree, ___ F.3d ___, No. 16-3298 (Northern District Iowa) (8th Cir. March 22, 2018),

in the context of trial conviction and application of federal sentencing enhancement under 21 USC Section 841—alcohol and heroin / jury instruction dispute:

“Given Dr. Goodin’s testimony that alcohol and metabolized heroin worked synergistically to cause CH’s death, but the level alcohol in his bloodstream by itself was not enough to cause death, no reasonable jury would have found that the heroin was a contributing factor, but not a but for cause of CH’s death. Dr. Goodin established at a minimum that, without the incremental effect of heroin distributed by Roundtree, CH would have lived.”
United States v. Seals, __ F.Supp.3d ___, No. 17-CR-28-LRR (Northern District Iowa US District Court, October 18, 2017, in the context of trial conviction and application of federal sentencing enhancement under 21 USC Section 841

Conviction upheld after fentanyl, acetylfentanyl, morphine, methamphetamine, and codeine were found in overdose patient’s toxicology, and AUSA charged “serious bodily injury resulted from “opiates”

Conviction was returned on causing serious bodily injury after ingestion of “opiates”, and judgment notwithstanding verdict denied.

“[A]lthough Dr. Pruitt was unable to state which particular substance caused JV’s injury, he concluded that ‘but for the use of an opiate, JV would not have suffered the injury (overdosed).’”
A GAME LIKE THIS, YOU'VE GOT TO TAKE ADVANTAGE OF YOUR OPPORTUNITIES.

Jim Christian
CURRENT CDC SOLICITATION:
FUNDING AMOUNT--$182,000,000.00

CDC-RFA-TP18-1802
Cooperative Agreement for Emergency Response: Public Health Crisis Response
2018 Opioid Overdose Crisis Cooperative Agreement Supplemental Guidance
June 20, 2018

I. Summary

The United States is in the midst of an opioid overdose epidemic. On average, 115 Americans die every day from an opioid overdose, and more than 630,000 people have died from a drug overdose from 1999 to 2016. In 2016, the number of overdose deaths involving opioids (including prescription opioids and illegal opioids like heroin and illicitly manufactured fentanyl) was five times higher than in 1999.

The FY 2018 Consolidated Appropriations Act and Accompanying Report includes an increase in funding appropriated to Centers for Disease Control and Prevention (CDC) to “advance the understanding of the opioid overdose epidemic and scale up prevention activities across all 50 States and Washington, D.C.” CDC will invite CDC-RFA-TP18-1802 Cooperative Agreement for Emergency Response: Public Health Crisis Response (https://www.cdc.gov/php/readiress/funding-crisis.htm) to award a portion of these funds to those affected by the opioid epidemic.

Supplemental guidance supplements guidance provided in the CDC-RFA-TP18-1802: Cooperative Agreement NOFO remain in effect unless otherwise amended herein. CDC reserves the right to change the administrative and technical guidance at any time.
## NIJ Past Grant Opportunities

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<tr>
<th>Grant Title</th>
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<th>Application Date</th>
<th>Maximum Amount</th>
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<td>2018-02-16</td>
<td>Up to $2,000,000.00</td>
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YOU DON’T HAVE TO DO THESE GRANTS, SOLICITATIONS, FUNDING OPPORTUNITIES, OR OTHER HUGE TASKS YOURSELF….

Forensic Toxicology Labs and Scientists
Emergency Departments and Physicians
Pretrial and Post-trial Supervision Departments
Epidemiology Experts
Treatment Providers
Public Health Labs

START FORMING THE PARTNERSHIPS NOW FOR NEXT YEAR’S OPPORTUNITIES….
NEVER APOLOGIZE FOR BEING TRUE TO YOURSELF.
Opioid pain relievers

- A. Are a late factor in the evolution of the current epidemic of opioid mortality
- B. Were less frequently prescribed the 1990s than previous decades
- C. Were reformulated to reduce abuse potential
- D. Are not addictive if used in the treatment of chronic pain
- E. Cannot be overprescribed if a patient reports they are still experiencing pain

POST TEST QUESTIONS
Heroin

- A. Is a Schedule II drug in the United States that has legitimate medical use but can be addictive
- B. Binds to the different receptors in the brain than the opioid pain relievers
- C. Is more expensive in street sales than fentanyl because heroin has a higher potency
- D. Is metabolized to morphine in the body
- E. Can only be used intravenously

POST TEST QUESTIONS
African-Americans

- A. Have recently seen rises in fentanyl overdose death rates
- B. Were more likely than whites to receive opioid pain relievers in the 1990-2005 era
- C. Only abuse cocaine
- D. Are less likely to respond to naloxone administration
- E. Frequently mix marijuana with carfentanil
The *Burrage* decision

- A. Sets mandatory minimum sentences for drug dealers
- B. Prevents prosecutions of overdose deaths where more than one drug is involved
- C. Prevents the overseas importation of illicitly manufactured drugs into the United States
- D. Requires that a drug distributed by a defendant be an independently sufficient ("but for") cause of the victim's death or serious bodily injury for imposition of penalty enhancements
- E. Directs the Drug Enforcement Agency to arrest only large scale drug distributors

**POST TEST QUESTIONS**
Carfentanil

- A. Is used for anesthesia in people undergoing heart surgery
- B. Cannot be treated with naloxone
- C. Has recently appeared in drug related deaths along with other analogues of fentanyl
- D. Is extracted from the poppy plant
- E. Is less potent than fentanyl

POST TEST QUESTIONS